



| Product  | Species               | Use levels  | Indications for use  |
|--|-----------------------|---|--|
| 10. Furazolidone and Bacitracin methylene disulfonate or Procaine penicillin | Chickens and turkeys: | 0.22 percent.....<br>do..... 4-50 g/ton;<br>do..... 2.4-50 g/ton; | For treatment of paratyphoid due to <i>S. typhimurium</i> when fed for 2 weeks. For treatment of blackhead ( <i>histomoniasis</i> , enterohepatitis) in chickens and turkeys when fed for 2 to 3 weeks (following diagnosis). For treatment of parvoe in chickens and turkeys and hexamitiasis in turkeys when fed for 2 weeks or longer (following diagnosis). For control of chronic respiratory disease (laryngitis), infectious sinusitis, synovitis (arthritis) due to <i>Mycoplasma</i> , and liver and gall disease (ulcerative enteritis) when fed for 5 to 10 days. For treatment of infectious hepatitis in chickens when fed for 14 days and repeated as necessary. |
|  |                       |   |  |

Interested persons may, on or before October 7, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 19, 1974.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.74-17221 Filed 8-5-74;8:45 am]

[ 21 CFR Part 135 ]

**ANTIBIOTIC, NITROFURAN, AND SULFONAMIDE DRUGS IN THE FEED OF ANIMALS**

**Notice of Proposed Rule Making**

An order was published in the FEDERAL REGISTER of April 20, 1973 (38 FR 9811), and amended in the FEDERAL REGISTER of September 5, 1973 (38 FR 23942), regarding, § 135.109, *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (21 CFR 135.109). The regulation was promulgated and amended following publication of notices of proposed rule making in the FEDERAL REGISTER of February 1, 1972 (37 FR 2444), and April 20, 1973 (38 FR 9830).

The regulation provides that the Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses of antibiotic, nitrofuran, and sulfonamide drugs in animal feeds by no later than 2 years following the effective dates of the orders, unless data are submitted which resolve conclusively issues which have been raised concerning the safety of such products to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA Task Force on Antibiotics in Animal Feeds. Of particular concern are those usages which provide for administration of antibacterial drugs over an extended period of time (approximately 14 days or longer).

Section 135.109 requires that all persons or firms previously marketing identical, related, or similar products not the subject of approved new animal drug

applications, shall have submitted for each such product a new animal drug application (NADA) by July 19, 1973, or, in the case of nitrofuran drugs, by December 4, 1973, if marketing is to continue during the interim. Persons or firms wishing to support the continued approval of such antibiotic, nitrofuran, and sulfonamide drugs shall submit, under the provisions of section 512(1) of the act, the following:

1. By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides, and for all other antibiotic drugs, by October 17, 1973; and for nitrofuran drugs by March 4, 1974.

2. By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin and the sulfonamides assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to withdraw approval.

3. By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir, for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofuran drugs, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for each individual or combination antibacterial drug product subject to § 135.109 and not reviewed by the NAS/NRC Veterinary Drug Efficacy Study Group.

4. Progress reports on studies underway every January 1 and July 1 until completion.

In response to § 135.109, the Commissioner has received satisfactory submissions from a number of producers of drug premixes as well as from several producers of intermediate premixes. Intermediate premixes are essentially drug premixes diluted to a lesser drug concentration. The production and distribution in interstate commerce of an intermediate premix which contains a new animal drug require an approved application pursuant to section 512(b) of the act. These applications fulfill the safety and efficacy data requirements through authorized reference to data contained in

the approved NADA covering the drug premix from which the intermediate premix is manufactured. It is conservatively estimated that there are over 10,000 intermediate premixes produced in the United States. As promulgated, the provisions of § 135.109 could be interpreted to require submissions from all intermediate premix manufacturers regarding the products they produce.

The Commissioner has concluded that, to avoid unnecessary duplication, § 135.109 should be amended to provide that at this time producers of intermediate premixes need not submit an NADA and data required under this section for the interim marketing of any intermediate premix produced solely from a premix that is in compliance with this section, if the intermediate premix contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where a specific premix has been approved by regulation in 21 CFR Part 135e as of the date specified in § 135.109(b)(1). Upon completion of the studies required by this section, a determination will be made regarding the need for applications for such products to provide for their continued use.

The Commissioner has also concluded that § 135.109 should be amended to list the manufacturers of antibacterial premixes who have satisfactorily responded to § 135.109 along with the corresponding premixes and combination drug products whose continued interim marketing and use will be permitted on the basis of their compliance with this section. Revocation of all other products subject to this section is proposed elsewhere in this issue of the FEDERAL REGISTER.

The claims provided below are on the basis of current use and may be subject to change based upon an evaluation of efficacy data by the National Academy of Sciences/National Research Council, Drug Efficacy Study Group or submitted in response to § 135.109.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 32 Stat. 343-351; (21 U.S.C. 360b, 371(a))) and under the authority delegated to the Commissioner (21 CFR 2.120), it is proposed that § 135.109 be amended by revising paragraph (a) and by adding a new paragraph (g) to read as follows:

**§ 135.109 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.**

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofuran drugs by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food

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and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofuran drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofuran drugs, if marketing is to continue during the interim. New animal

drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

\* \* \* \*

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any intermediate premix which is produced solely from a premix that is in compliance with

the requirements of this section: Provided, That the intermediate premix contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the premix is approved by regulation in Part 135e of this chapter.

(1) The following antibacterial drug premixes manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

| Drug sponsor  | Drug premix                                       | Species                              | Use levels  | Indications for use   |
|---|---|--------------------------------------|---|---|
| Commercial Solvents Corp.   | Zinc bacitracin                                   | Chickens, turkeys, and swine         | § 121.233 (tables 1 and 2) of this chapter                      | § 121.233 (tables 1 and 2) of this chapter.   |
| Do.   | do.   | do                                   | § 121.235 of this chapter                                       | § 121.235 of this chapter.  |
| B. Penick & Co.   | Bacitracin methylene salicylate                   | Cattle, chickens, turkeys, and swine | § 121.232 (tables 1 and 2) of this chapter                      | § 121.232 (tables 1 and 2) of this chapter.   |
| Do.   | do.   | do                                   | § 121.235 of this chapter                                       | § 121.235 of this chapter.  |
| Elanco Products Co.   | Hygromycin B                                      | Chickens and swine                   | § 121.232 (tables 1 and 2) of this chapter                      | § 121.233 (tables 1 and 2) of this chapter.   |
| Do.   | Tylosin   | Swine                                | § 1350.10 of this chapter                                       | § 1350.10 of this chapter.  |
| Abbott Laboratories   | Erythromycin                                      | Chickens, turkeys, and swine         | § 121.232 of this chapter                                       | § 121.232 of this chapter.  |
| The Upjohn Co.  | Lincomycin  | Chickens                             | § 1350.49 of this chapter                                       | § 1350.49 of this chapter.  |
| Pfizer, Inc.  | Oleandomycin                                      | Chickens and swine                   | § 1350.46 of this chapter                                       | § 1350.46 of this chapter.  |
| Hoechst Pharmaceuticals   | Bambermycin                                       | Chickens                             | § 1350.46 of this chapter                                       | § 1350.46 of this chapter.  |
| American Cyanamid Co., Diamond Shamrock Chemical Co., Hess and Clark, Rachelle Labs, Inc., and Vitamin Premixers of Omaha | Chlortetracycline                                 | Chickens, turkeys, swine, and cattle | § 121.233 (tables 1, 2, and 6) of this chapter                  | § 121.233 (tables 1, 2, and 6) of this chapter.   |
| Do.   | do.   | do                                   | § 121.235 of this chapter                                       | § 121.235 of this chapter.  |
| Merck, Sharpe & Dohme Research Labs.  | Procaine penicillin                               | Chickens, turkeys, and swine         | § 121.233 (tables 1 and 2) of this chapter                      | § 121.233 (tables 1 and 2) of this chapter.   |
| Do.   | do.   | do                                   | § 121.235 of this chapter                                       | § 121.235 of this chapter.  |
| E. R. Squibb & Sons, Inc.   | do.   | Pheasant and quail                   | Continuously, 0.0125-0.25 percent                               | do.   |
| Merck, Sharpe, & Dohme Research Labs.   | Sulfoxquinavolino                                 | Chickens                             | Continuously, 0.0125-0.25 percent                               | Aid in prevention of coccidioides due to <i>Escherichia coli</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. maxima</i> .  |
| Do.   | do.   | Turkeys                              | Continuously, 0.0175 percent                                    | Aid in prevention of coccidioides due to <i>Escherichia coli</i> , <i>E. necatrix</i> and <i>E. acervulina</i> .  |
| Do.   | do.   | Rabbits                              | Continuously, 0.025 percent                                     | Aid in prevention of coccidioides due to <i>Escherichia coli</i> , <i>E. perforans</i> .  |
| Pfizer, Inc., and Vitamin Pre-mixers of Omaha   | Oxytetracycline                                   | Chickens and turkeys                 | § 121.231 (table 1) of this chapter                             | § 121.231 (table 1) of this chapter.  |
| Do.   | do.   | Swine (10-30 lb)                     | 25-50 mg/ton  | To increase rate of gain and improve feed efficiency.   |
| Do.   | do.   | Chickens and turkeys                 | 7/4-10 g/ton  | do.   |
| Do.   | do.   | Swine (30-200 lb)                    | 20 g/ton  | As an aid in the prevention of bacterial enteritis, also known as scours, baby pig diarrhea, vibrio dysentery, bloody dysentery and salmonellosis (necro or necrotic enteritis).  |
| Do.   | do.   | Calves                               | 25-75 mg/head per day or in complete feed at 50 g/ton           | To increase rate of gain and improve feed efficiency.   |
| Do.   | do.   | Cattle                               | 75 mg/head daily  | As an aid in the prevention of bacterial diarrhea.  |
| Do.   | do.   | do                                   | 0.1-0.5 mg/lb of bodyweight daily                               | As an aid in reducing incidence and severity of bloat. As an aid in reducing incidence and severity of liver abscesses (for cattle weighing over 400 lb).   |
| Hoffmann-La Roche, Inc.   | Sulfadimethoxine and Oxytetracycline              | Chickens and turkeys                 | § 1350.53 of this chapter                                       | As an aid in the prevention of bacterial diarrhea.  |
| Pfizer, Inc.  | Chlortetracycline and Neomycin                    | Chickens, turkeys, swine, and calves | As provided in par. (g)(2) of this section                      | As provided in par. (g)(2) of this section.   |
| American Cyanamid Co. and Chlortetracycline, Sulfa-methazine, and Penicillin  | Sulfa-methazine, and Penicillin                   | Swine                                | do  | do.   |
| Diamond Shamrock Chemical Co.   | Chlortetracycline, Sulfa-thiazole, and Fomocillin | do                                   | do  | do.   |
| Hess & Clark and Norwich Pharmacal Co.  | Furazolidone                                      | Chickens and turkeys                 | 0.00033-0.0011 percent (74-10 g/ton); 0.0055 percent (50 g/ton) | To stimulate growth and improve feed efficiency of chickens and turkeys when fed continuously. For prevention of fowl typhoid, paratyphoid, and pullorum in chickens and turkeys when fed continuously in birds older than 2 weeks of age. For aid in prevention of coccidioides in chickens caused by <i>E. coli</i> , <i>E. necatrix</i> , or <i>E. acervulina</i> when fed continuously.   |
| Do.   | do.   | do                                   | 0.0055 percent (50 g/ton)                                       | To aid in maintenance of feed consumption and growth and reduction of morbidity and mortality due to stress and the following nonspecific conditions: Chronic respiratory disease (bilateral), Infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (bluecomb, mud fever) and quail disease (degenerative enteritis) when fed continuously prior to or throughout the danger period and during times of stress. |
| Do.   | do.   | do                                   | 0.0055-0.011 percent (50-100 g/ton)                             | For prevention of fowl typhoid, paratyphoid and pullorum in chickens and turkeys when fed for the first 2 weeks of the birds' life and follow continuously thereafter by one-half this level (i.e., 0.0055 percent). For treatment of fowl typhoid, paratyphoid and pullorum in chickens and turkeys when fed for at least 2 weeks except when paratyphoid is due to <i>S. typhimurium</i> .  |
| Do.   | do.   | do                                   | 0.011 percent (100 g/ton)                                       | do.   |

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| Drug sponsor | Drug ingredient | Species  | Use levels                          | Indications for use   |
|--------------|-----------------|----------|-------------------------------------|---|
| Do.          | do              | do       | do                                  | For reduction of condemnations due to chronic respiratory disease disease complex associated with vaccination stress, feed continuously beginning at least 1 week before vaccination. For prevention of infectious hepatitis when fed continuously during the danger period. For control of coccidiosis in chickens caused by <i>E. tenella</i> , <i>A. megastigma</i> , or <i>E. acervulina</i> when fed for 5-7 days or longer and followed by one-half this level (i.e., 0.013 percent) for 2 weeks to aid in preventing recurrence.   |
| Do.          | do              | do       | do                                  | For prevention of blackhead (histomoniasis, enterohelminthiasis) in chickens and turkeys when fed continuously. For prevention of paracoccidioides in chickens and turkeys and laminitis in turkeys when fed throughout the danger period. For control of chronic respiratory disease (laryngeal), infectious sinusitis, synovitis (arthritits due to a filtrable agent), nonspecific enteritis (bluecomb, mud fever) and quill disease (infectious enteritis) when fed for 5-10 days and followed with one-half this level (i.e., 0.013 percent) to aid in preventing recurrence. Note—Severe outbreaks may require twice the level specified (i.e., 0.026 percent).   |
| Do.          | do              | do       | 0.011-0.022 percent (100-200 g/ton) | Aid in maintenance of feed consumption and growth, and reduction of mortality and morbidity due to stress for the control of the following nonspecific conditions: Chronic respiratory disease (laryngeal), Infectious sinusitis, synovitis (arthritis due to a filtrable agent), nonspecific enteritis (bluecomb, mud fever) and quill disease (infectious enteritis) when fed 5-10 days. Follow with preventive level to prevent recurrence.  |
| Do.          | do              | Chickens | 0.022 percent (200 g/ton)           | For treatment of paratyphoid due to <i>S. typhimurium</i> when fed for 2 weeks. For treatment of blackhead (histomoniasis, enterohelminthiasis) in chickens and turkeys when fed for 2-3 weeks (laryngeal disease). For treatment of paracoccidioides in chickens and turkeys and laminitis in turkeys when fed for 2 weeks or longer (laryngeal disease). For control of chronic respiratory disease (laryngeal), infectious sinusitis, synovitis (arthritis due to a filtrable agent), nonspecific enteritis (bluecomb, mud fever) and quill disease (infectious enteritis) when fed for 5-10 days and followed with one-half this level (i.e., 0.013 percent) to aid in preventing recurrence. For treatment of infectious hepatitis in chickens when fed for 14 days and repeated as necessary. |
| Do.          | Nitrofurazone   | Swine    | \$ 121.265 of this chapter          | \$ 121.265 of this chapter.   |
| Do.          | Nitrofurazone   | Chickens | 0.0035 percent (50 g/ton)           | Aid in prevention of coccidiosis when fed continuously.   |
| Do.          | do              | Turkeys  | do                                  | As an aid in controlling losses due to secondary bacterial infections concurrent with coccidiosis outbreaks when fed continuously throughout the danger period.   |
| Do.          | Nihydrazone     | Chickens | \$ 121.237 of this chapter          | \$ 121.237 of this chapter.   |

(2) The following drug combinations are permitted when prepared from the antibacterial drug premixes listed in paragraph (g)(1) of this section:

| Drug sponsor                                  | Drug ingredient                       | Species                  | Use levels                            | Indications for use   |
|---|---------------------------------------|--------------------------|---------------------------------------|---|
| American Cyanamid Co. and Research Labs, Inc. | Chlorotetracycline                    | Swine                    | 100 g/ton                             | \$ 135.61 of this chapter.  |
| Do.   | Sulfamethazine                        | do                       | do                                    | Do.   |
| Do.   | Penicillin                            | do                       | 50 g/ton                              | Do.   |
| Diamond Shamrock Chemical Co.                 | Chlorotetracycline                    | do                       | 100 g/ton                             | \$ 135.63 of this chapter.  |
| Do.   | Sulphonizole                          | do                       | do                                    | Do.   |
| Do.   | Penicillin                            | do                       | 50 g/ton                              | Do.   |
| American Cyanamid Co.                         | Chlorotetracycline and Sulfamethazine | Cattle                   | \$ 121.263 (Table 6) of this chapter. | \$ 121.263 (Table 6) of this chapter.   |
| Pfizer, Inc. and Vitamin Pre-mixers of Omaha  | Oxytetracycline                       | Chickens                 | 50 g/ton                              | Prevention of diseases from oxytetracycline-susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of monogram-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).  |
| Do.   | Neomycin base                         | do                       | 35-140 g/ton                          | Do.   |
| Do.   | Oxytetracycline                       | Chickens                 | 50-100 g/ton                          | Prevention of early chick mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of monogram-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).  |
| Do.   | Neomycin base                         | Chickens (first 2 weeks) | 35-140 g/ton                          | Do.   |
| Do.   | Oxytetracycline                       | Chickens                 | 50-100 g/ton                          | To extend period of high egg production, to improve feed efficiency, to improve egg production and feed efficiency in presence of disease and at times of stress. As an aid in maintaining and improving hatchability where birds are suffering stress from moving, vaccinations, calling, extreme temperature changes, and warming; to improve hatchability of progeny when hens are due to oxytetracycline-susceptible organisms; to improve egg shell quality, prevention of blue comb (mud fever or nonspecific enteritis). As an aid in the prevention of bacterial enteritis and in the control of monogram-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis). |
| Do.   | Neomycin base                         | do                       | 35-140 g/ton                          | Do.   |

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| Principal ingredient                            | Grams per ton   | Combined with—               | Grams per ton | Limitations   | Indications for use  |
|---|---|------------------------------|---------------|---|--|
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 100-200 g/ton.....                                    | Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluetomb (mud fever or nonspecific enteritis).   |
| Pfizer, Inc.....                                | Neomycin base.....  | do.....                      | do.....       | 35-140 g/ton.....                                     | As an aid in the prevention of disease from oxytetracycline-susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluetomb (mud fever or nonspecific enteritis).   |
| Do.....   | Oxytetracycline.....  | Turkeys.....                 | do.....       | 50 g/ton.....   | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 35-140 g/ton.....                                     | To extend period of high egg production, to improve egg production, to improve feed efficiency, to improve fertility, to improve egg production and feed efficiency in presence of disease and time of stress; as an aid in maintaining and improving hatchability where birds are suffering from stress, exposure, moving, vaccination, culling, extreme losses due to oxytetracycline-susceptible organisms, and to improve egg shell quality; prevention of laminitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluetomb (mud fever or nonspecific enteritis). |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 50-100 g/ton.....                                     | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 35-140 g/ton.....                                     | As an aid in the prevention of early poult mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluetomb (mud fever or nonspecific enteritis).  |
| Do.....   | Oxytetracycline.....  | Turkeys (first 4 weeks)..... | do.....       | 35-140 g/ton.....                                     | Do.  |
| Do.....   | Neomycin base.....  | Turkeys.....                 | do.....       | 100-150 g/ton.....                                    | As an aid in reducing mortality in birds which have suffered an attack of air-sacculitis (it is recommended, wherever possible, to feed from time of attack to marketing).   |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 35-100 g/ton.....                                     | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 100-150 g/ton.....                                    | As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluetomb (mud fever or nonspecific enteritis).   |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 35-100 g/ton.....                                     | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 100-200 g/ton.....                                    | Control of bluetomb (mud fever or nonspecific enteritis), infectious sinusitis and laminitis, prevention of infectious synovitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluetomb (mud fever or nonspecific enteritis).   |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 200 g/ton.....  | Do.  |
| Pfizer, Inc., and Vitamin Pre- mixers of Omaha: | Neomycin base.....  | do.....                      | do.....       | 70-140 g/ton.....                                     | Control of infectious synovitis. For the treatment of bacterial enteritis and bluetomb (mud fever or nonspecific enteritis).   |
| Do.....   | Oxytetracycline.....  | Swine.....                   | do.....       | 50 g/ton.....   | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 35-140 g/ton.....                                     | As an aid in the prevention of bacterial enteritis (scours), baby pig diarrhea (in baby pigs only), vibrionic dysentery, bloody dysentery and salmonellosis (ulcer or necrotic enteritis).   |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 50-150 g/ton.....                                     | Do.  |
| Pfizer, Inc.....                                | Neomycin base.....  | Calves.....                  | do.....       | 70-140 g/ton.....                                     | As an aid in the prevention of bacterial enteritis (scours).   |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 50 g/ton.....   | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 35-140 g/ton.....                                     | As an aid in the treatment of bacterial enteritis (scours).  |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 100 g/ton.....  | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 70-140 g/ton.....                                     | As an aid in the prevention of bacterial diarrhea (scours).  |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 8-100 mg/gal reconstituted milk replacer.....         | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 100-200 mg/gal reconstituted milk replacer.....       | As an aid in the prevention of bacterial diarrhea (scours).  |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 40-200 mg/gal reconstituted milk replacer.....        | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | 200-400 mg/gal reconstituted milk replacer.....       | Do.  |
| Do.....   | Oxytetracycline.....  | do.....                      | do.....       | 5 § 135e.36 of this chapter.....                      | Do.  |
| Do.....   | Neomycin base.....  | do.....                      | do.....       | § 135e.49 and 121.210 of this chapter.....            | Do.  |
| Elanco Products Co.....                         | Tylosin and sulfamethazine. Swine.....  | do.....                      | do.....       | § 135e.36.  |  |
| The Upjohn Co.....                              | Lincomycin, amprolium, Chickens and ethopabate.....                             | do.....                      | do.....       | § 135e.49 and 121.210 of this chapter.....            | § 135e.49 and 121.210.   |
| Do.....   | Lincomycin and buquinolate.....   | do.....                      | do.....       | § 135e.49 and 135e.24 of this chapter.....            | § 135e.49 and 135e.31.   |
| Do.....   | Lincomycin and clopidol.....  | do.....                      | do.....       | § 135e.49 and 135e.46 of this chapter.....            | § 135e.49 and 135e.46.   |
| Do.....   | Lincomycin and decoquinate.....   | do.....                      | do.....       | § 135e.49 and 135e.51 of this chapter.....            | § 135e.49 and 135e.51.   |
| Do.....   | Lincomycin and zoalene.....   | do.....                      | do.....       | § 135e.49 and 121.207 of this chapter.....            | § 135e.49 and 121.207.   |
| Do.....   | Lincomycin, amprolium, ethopabate, and 3-nitro-4-hydroxyphenylarsonic acid..... | do.....                      | do.....       | § 135e.49, 121.210, and 121- 262 of this chapter..... | § 135e.49, 121.210, and 121- 262 of this chapter.  |
| Do.....   | Lincomycin and monensin.....  | do.....                      | do.....       | § 135e.49 and 135e.50 of this chapter.....            | § 135e.49 and 135e.50.   |
| Do.....   | Lincomycin and robenidine hydrochloride.....                                    | do.....                      | do.....       | § 135e.49 and 135e.60 of this chapter.....            | § 135e.49 and 135e.60.   |
| Do.....   | Lincomycin, monensin, and 3-nitro-4-hydroxyphenylarsonic acid.....              | do.....                      | do.....       | § 135e.49, 135e.50, and 121- 262 of this chapter..... | § 135e.49, 135e.50, and 121.262.   |

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| Principal ingredient                 | Grams per ton | Combined with—                      | Grams per ton        | Limitations                           | Indications for use                   |
|--------------------------------------|---------------|-------------------------------------|----------------------|---------------------------------------|---------------------------------------|
| Merck, Sharpe & Dohme Research Labs. |               | Procaine penicillin                 | Chickens and turkeys | 2.4-7.5 g/ton                         | § 121.23(a)(3)(iv) of this chapter    |
| Do                                   |               | Streptomycin                        | do                   | 12.0-37.5 g/ton                       | Do.                                   |
| Do                                   |               | Procaine penicillin                 | Chickens             | 3.0-7.5 g/ton                         | Do.                                   |
| Do                                   |               | Streptomycin                        | do                   | 15.0-37.5 g/ton                       | Do.                                   |
| Do                                   |               | Procaine penicillin                 | Swine                | 1.5-7.5 g/ton                         | § 121.23(a)(3)(vi) of this chapter    |
| Do                                   |               | Streptomycin                        | do                   | 7.5-37.5 g/ton                        | Do.                                   |
| Do                                   |               | Procaine penicillin                 | do                   | 7.5-15 g/ton                          | § 121.23 (table 2) of this chapter    |
| Do                                   |               | Streptomycin                        | do                   | 31.5-75.0 g/ton                       | Do.                                   |
| Do                                   |               | Procaine penicillin                 | do                   | 1.5-7.5 g/ton                         | § 141.23 of this chapter              |
| Do                                   |               | Streptomycin                        | do                   | 7.5-37.5 g/ton                        | Do.                                   |
| Do                                   |               | Arsanilic acid                      | do                   | 45-60 g/ton                           | Do.                                   |
| Do                                   |               | Nicarbazin                          | Chickens             | 0.01-0.02 percent                     | Do.                                   |
| Do                                   |               | Procaine penicillin                 | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | Nicarbazin                          | do                   | 0.01-0.02 percent                     | § 141.23 of this chapter              |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Nicarbazin                          | do                   | 0.01-0.02 percent                     | Do.                                   |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 1.0 g/ton                             | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.0025-0.003 percent                  | Do.                                   |
| Do                                   |               | Nicarbazin                          | do                   | 0.01-0.02 percent                     | Do.                                   |
| Do                                   |               | Procaine penicillin                 | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.0025-0.003 percent                  | Do.                                   |
| Do                                   |               | Amprolium                           | Chickens and turkeys | 0.0125-0.025 percent                  | § 121.210 of this chapter             |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Amprolium                           | Chickens             | 0.0125-0.025 percent                  | Do.                                   |
| Do                                   |               | Ethopabate                          | do                   | 0.0031 percent                        | Do.                                   |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Amprolium                           | do                   | 0.0125-0.025 percent                  | § 121.210 and 121.232 of this chapter |
| Do                                   |               | Ethopabate                          | do                   | 0.0031 percent                        | Do.                                   |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.0025-0.003 percent                  | Do.                                   |
| Do                                   |               | Amprolium                           | Chickens and turkeys | 0.01-0.025                            | § 121.210 of this chapter             |
| Do                                   |               | Procaine penicillin                 | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | Amprolium                           | Chickens             | 0.01-0.025 percent                    | § 121.210 and 121.232 of this chapter |
| Do                                   |               | Procaine penicillin                 | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.0025 percent                        | Do.                                   |
| Pfizer, Inc.                         |               | Amprolium                           | do                   | 0.0125-0.0125 percent                 | § 121.210 of this chapter             |
| Do                                   |               | Procaine penicillin                 | do                   | 0.0031 percent                        | Do.                                   |
| Do                                   |               | Amprolium                           | do                   | 0.0125-0.025 percent                  | § 121.210 and 121.232 of this chapter |
| Do                                   |               | Ethopabate                          | do                   | 0.0031 percent                        | Do.                                   |
| Hoffmann-La Roche, Inc.              |               | Bacitracin methylene di-salicylate  | Chickens             | 1.0 g/ton                             | § 131.23 of this chapter              |
| Do                                   |               | Ormetoprim                          | do                   | do                                    | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | do                                    | Do.                                   |
| Do                                   |               | Sulfadimethoxine                    | Turkeys              | § 132.25 and § 133.25 of this chapter | § 132.25 and § 133.25 of this chapter |
| Dow Chemical Co.                     |               | Ormetoprim                          | do                   | do                                    | Do.                                   |
| Do                                   |               | Ipronidazole                        | do                   | do                                    | Do.                                   |
| Do                                   |               | Zoledene                            | Chickens             | 0.0125 percent                        | § 121.207 of this chapter             |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.003 percent                         | Do.                                   |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | Zinc bacitracin                     | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | Penicillin                          | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.003 percent                         | Do.                                   |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | Arsanilic acid                      | do                   | 0.01 percent                          | Do.                                   |
| Do                                   |               | Penicillin                          | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125-0.0125 percent                 | Do.                                   |
| Do                                   |               | Bacitracin methylene di-salicylate  | do                   | 4-30 g/ton                            | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | Penicillin                          | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.003 percent                         | Do.                                   |
| Do                                   |               | Penicillin                          | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | Penicillin                          | do                   | 2.4-3.0 g/ton                         | Do.                                   |
| Do                                   |               | Zoledene                            | do                   | 0.0125 percent                        | Do.                                   |
| Do                                   |               | 3-Nitro-4-hydroxyphenylarsonic acid | do                   | 0.003 percent                         | Do.                                   |
| Do                                   |               | Penicillin                          | do                   | 2.4-3.0 g/ton                         | Do.                                   |

## PROPOSED RULES

| Drug sponsor          | Drug ingredient                      | Species              | Use levels                          | Indications for use   |
|-----------------------|--------------------------------------|----------------------|-------------------------------------|---|
| Do.                   | Zoalene                              | do                   | 0.0125 percent                      | Do.   |
| Do.                   | Arsanilic acid                       | do                   | 0.01 percent                        | Do.   |
| Do.                   | Bacitracin methylene di-salicylate   | do                   | 4-50 g/ton                          | Do.   |
| Do.                   | Zoalene                              | do                   | 0.0125 percent                      | Do.   |
| Do.                   | Arsanilic acid                       | do                   | 0.01 percent                        | Do.   |
| Do.                   | Penicillin                           | do                   | 2.4-50 g/ton                        | Do.   |
| Do.                   | Zoalene                              | do                   | 0.004-0.0125 percent                | Do.   |
| Do.                   | Bacitracin methylene di-salicylate   | do                   | 4-50 g/ton                          | Do.   |
| Do.                   | Zoalene                              | do                   | 0.004-0.0125 percent                | Do.   |
| Do.                   | 3-Nitro-4-hydroxyphenyl-arsonic acid | do                   | 0.005 percent                       | Do.   |
| Do.                   | Bacitracin methylene di-salicylate   | do                   | 4-50 g/ton                          | Do.   |
| Norwich Pharmacal Co. | Furazolidone                         | Swine                | 0.022 percent (200 g/ton)           | Prevention of bacterial enteritis (necrotic enteritis, necro) and vibriotic (bloody) dysentery growth promotion while on medication when fed in prestarters, starters and growing rations to baby pigs and growing swine for 2 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis. |
| Do.                   | Oxytetracycline                      | do                   | 50-150 g/ton                        | Do.   |
| Do.                   | Furazolidone                         | do                   | 0.11 percent (100 g/ton)            | Prevention of bacterial enteritis (necrotic enteritis, necro) and vibriotic (bloody) dysentery growth promotion while on medication when fed in prestarters, starters and growing rations to baby pigs and growing swine for 6 weeks.   |
| Do.                   | Oxytetracycline                      | do                   | 50-100 g/ton                        | Do.   |
| Do.                   | Arsanilic acid                       | do                   | 0.003-0.01 percent                  | As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis.   |
| Do.                   | Furazolidone                         | Chickens and turkeys | 0.011-0.022 percent (100-200 g/ton) | Growth promotion and feed efficiency. § 121.23 of this chapter.   |
| Do.                   | Bacitracin methylene di-salicylate   | do                   | 4-50 g/ton                          | Do.   |
| Do.                   | Zinc bacitracin                      | do                   | do                                  | Do.   |
| Do.                   | Procaine penicillin                  | do                   | 2.4-50 g/ton                        | Do.   |
| Do.                   | Nihydrzone                           | Chickens             | 0.11 percent (100 g/ton)            | § 121.23 of this chapter.   |
| Do.                   | Procaine penicillin                  | do                   | 2.4-50 g/ton                        | Do.   |
| Do.                   | Nihydrzone                           | do                   | 0.11 percent (100 g/ton)            | Do.   |
| Do.                   | Chlortetracycline                    | do                   | 10-40 g/ton                         | Do.   |
| Do.                   | Nihydrzone                           | do                   | 0.11 percent (100 g/ton)            | Do.   |
| Do.                   | Bacitracin methylene disalicylate    | do                   | 4-50 g/ton                          | Do.   |
| Do.                   | Zinc bacitracin                      | do                   | do                                  | Do.   |

Interested persons may, on or before October 7, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this pro-

posal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 19, 1974.

SARL D. FIRE,  
Associate Commissioner  
for Compliance.

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